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(12) Patent:

strategis.gc.ca

Application Number:

11/05/2002 - 18:32:39

(11) CA 1239583

(21) 475883

- (54) METHOD OF INACTIVATING REPRODUCIBLE FILTERABLE PATHOGENS IN BLOOD PRODUCTS AS WELL AS A METHOD OF PRODUCING BLOOD PRODUCTS
- (54) METHODE D'INACTIVATION DE PATHOGENES FILTRABLES DANS LES PRODUITS SANGUINS ET METHODE DE PRODUCTION DE PRODUITS SANGUINS

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ABSTRACT:

ABSTRACT OF THE DISCLOSURE:

A method of inactivating viruses in blood products is described, wherein the blood products are heat-treated in a humid or in a solid state in the presence of inorganic or organic hydroxyl group-containing compounds having an H+dissociation constant of < 10-11 in a concentration of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight). The hydroxyl group-containing compounds may be water, methanol, or ethanol. The temperature may amount up to 121°C, the heat treatment may last from 1 s to 100 h. The inactivation method may be applied for producing blood products selected from enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibronectin or plasma, the inactivation destroying any reproducible filterable pathogens that might be present.

CLAIMS: Show all claims

*** Note: Data on abstracts and claims is shown in the official language in which it was submitted.

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N/A

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THE EMBODIMENTS BY THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OF PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

- I. A method of inactivating viable filterable pathogens in blood products under application of an elevated temperature, characterized in that the blood products, in a solid state, are adjusted to a content of water, methanol or othered of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight) and are treated in a closed container at a temperature causing from 50 to 121°C, while maintaining the blood products in their solid state and while increasing the partial vapor pressure of water, methanol or otheres.
- A method as set forth in claim 1, wherein the blood products are adjusted to a content of water, methanol or ethanol of less than 0.40 (40 % by weight).
- 3. A method as set forth in claim 1, wherein the blood products are treated with water vapor at a pressure of from 0.1 to 2 bar.
- A method as set forth in claim 1, wherein said viable filterable pathogens are hepatitic viruses.
- 5. A method as set forth in claim 1, wherein said viable filterable pathogens are agents capable of transmitting AIDS (acquired immune deficiency syndrome).

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The invention relates to a method of inactivating viabl filterable pathogens, in particular hepatitis viruses and pathogens which may be able to transmit AIDS (acquiredimmune deficiency syndrome), in blood products by using an elevated temperature, as well as to a method of producing blood products by using this method.

By blood products, products of human or animal blood or plasma are meant which are intended for a therapeutic, prophylactic or diagnostic use. Such products may contain enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobuting, albumin, plasminogen, fibrinogen, fibrinogen, fibronectic or plasma.

There are abundant publications doaling with the thermal inactivation of reproducible filterable pathogons in blood products.

The various methods include:

- heating of the blood products in equeous solution, if desired, with the addition of virucidal substances,
- heating of the blood products in aqueous solution in the presence of stabilizing agents.
 - treating the blood products with organic solvents,
 - irradiating the blood products in the solid state,
 - heating of the blood products in the dry state.

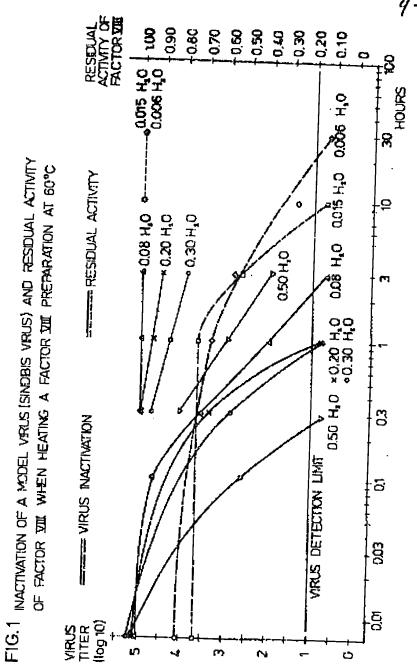
All these inactivation methods sim at destroying the potential infectivity of the preparations while substantially maintaining their biological activity. By to now, however, this aim could be achieved only with albumin preparations, i.e. by heating aqueous albumin solutions at a temperature of 50°C for 10 hours, since albumin is considerably more stable towards heat than all other blood

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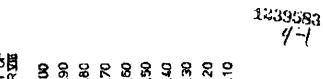
ABSTRACT OF THE DISCLOSURE:

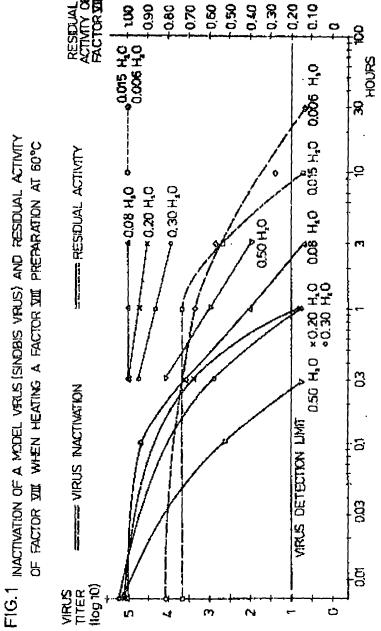
A method of inactivating viruses in blood products is described, wherein the blood products are heat-treated in a humid or in a solid state in the presence of inorganic or organic hydroxyl group-containing compounds having an H+discociation constant of < 10-11 in a concentration of more than 0.05 (5 % by weight) and less than 0.70 (70 % by weight). The hydroxyl group-containing compounds may be water, methanol, or othanol. The temperature may amount up to 121°C, the heat treatment may last from 1 ϵ to 100 h. The inactivation method may be applied for producing blood products sclected from enzymes, proenzymes including congulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibrinectin or plasma, the inactivation destroying any reproducible filterable pathogens that might be present.





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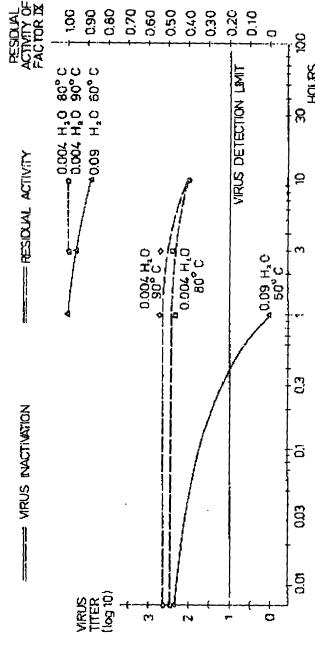




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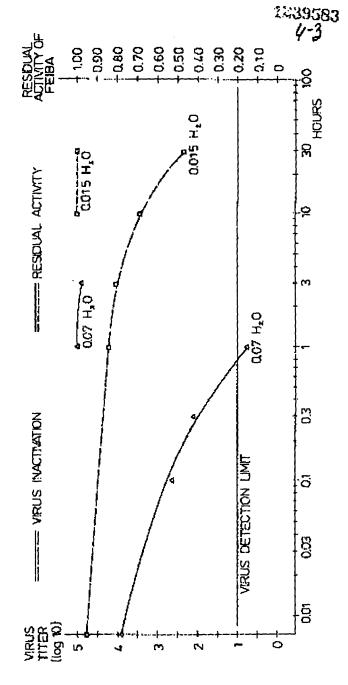
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INACTIVATION OF A MODEL VIRUS (CANINE HERATITIS VIRUS) AND FEB-RESIDUAL ACTIVITY WHEN HEATING A FEIBA PREPARATION AT 60°C FIG. 3



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FIG. 4





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